

REMARKS

Claims 1-22 are currently pending in the instant application. Applicants have amended Claims 1, 4, 11, and 21. Support for amended claims 1, 4, 11, and 21 and new claim 22 may be found in the claims and specification as filed, in particular at page 4, lines 6-9 and in Examples 1-5.

In the Advisory Action, dated May 29, 2003, the Examiner maintained the rejection of claims 1-2, 4-5, 9-13, and 16-20 under 35 U.S.C. § 102(b) as being anticipated by Cingotti, and the Examiner maintained the rejection of claims 3, 6-8, 14-15, and 21 under 35 U.S.C. § 103(a) as being unpatentable over Cingotti and Menzi in view of Breitenbach. Applicants respectfully request that the Examiner reconsider the rejections in view of the foregoing amendment and the following response.

The granules and methods as recited in the amended claims are distinguished from the cited art, including Cingotti, Menzi, and Breitenbach, for several reasons. First, the claims have been amended to indicate that the granules include a neutral core and a layer that comprises polyvinylpyrrolidone (PVP) as a binder, as recited in independent claims 1, 11, and 22. None of the prior art references teach or suggest granules that include all the limitations of the claims as amended.

Cingotti does not teach or suggest neutral cores of the recited core size (*i.e.*, 200 and 1600  $\mu\text{m}$ ), which are coated with a plant substance and PVP as a binder. Further, Cingotti teaches away from coating neutral cores of the recited core size with a plant substance and PVP as a binder, where at column 5, Example 5, Cingotti states that “direct impregnation of the sorbitol microgranules [*i.e.*, cores between 100 and 1000  $\mu\text{m}$ ] with the hydroalcoholic solution [results in a] congealed mass...that is impossible to homogenize, dry and gauge.”

Therefore, Cingotti teaches away from the recited granules and methods. Furthermore, the proposed modification, (*i.e.*, using PVP as a binder), renders Cingotti unsatisfactory for Cingotti's intended purpose and changes the principle of operation of Cingotti. As such, Cingotti is not a proper reference for a *prima facie* case of obviousness. See MPEP § 2143 and 2143.01.

While Menzi may suggest coating particles with a solution that may include PVP, Menzi clearly states that the active ingredient is sprayed into the core material which is then granulized to form the particles, where Menzi states "[t]he novel process is characterized by spraying a flavorant or odorant emulsion into a core material fluidized in a fluidized rotor-granulator, the emulsion being sprayed into the fluidized bed below the surface of the core material and the emulsion being granulated in this matter." At Figure 1, Menzi clearly shows that the active ingredient is incorporated in and throughout the coated core to form heterogenous particles that contain the active ingredient. As such, Menzi does not teach a neutral core coated with a plant substance, as recited in claims 1, 11, and 22. Further, the amended claims recite granules that have unique and desirable characteristics. As indicated in the instant specification at page 2, lines 7-9, "[t]he multiparticulate form of the formulation of the invention makes it possible to obtain a uniform and reproducible release profile." Because Menzi does not teach a neutral core, but rather teaches a core in which the active ingredient has been sprayed into a core material to produce heterogenous particles, Menzi's particles will not have the same release profile as the granules as recited in claims 1, 11, and 22. In addition, Menzi teaches particles which have been formed by granulation. During Menzi's granulation method, the particles form when the core material agglomerates with the

aid of the emulsion. As such, Menzi, does not teach or suggest granules with a neutral core and an active layer as recited in the amended claims.

Likewise, Breitenbach does not teach or suggest neutral cores. Rather, Breitenbach teaches coextrusion of at least two compositions to produce a drug form, where at least one composition includes the active ingredient. Therefore, Breitenbach does not teach or suggest neutral cores because Breitenbach's active ingredient is present in the core. See U.S. 6,120,802, col. 3, lines 4-5 ("including the active ingredient in the inner layer(s)"); *id.*, Example 1 ("core containing active ingredients"), Example 2 ("Tablets which contain ibuprofen in the core"), Example 3 ("core with a low release rate" for paracetamol), Example 4 ("hydroxypropylcellulose layer" with "nifedipine as active ingredient...surrounded on both sides..."), Example 5 ("active ingredient dispersed in the PVP core"), Example 6 ("hydroxypropylcellulose core with a low release rate"), Example 7 ("PCP core containing active ingredient"), Example 8 ("core containing active ingredient"), and Example 9 ("core with vitamin A and E"). Because Breitenbach does not teach a neutral core, but rather teaches a core in which the active ingredient has been coextruded, Breitenbach's particles will not have the same characteristic as the granules as recited in claims 1, 11, and 22.

In summary, because Cingotti does not teach all the limitations of the amended claims, Applicants respectfully request that the Examiner reconsider the rejection under 35 U.S.C. § 102(b). Further, because Cingotti does not teach all the limitations of the amended claims and because Cingotti is not a proper reference for a *prima facie* case of obviousness, Applicants respectfully request that the Examiner reconsider the rejection under 35 U.S.C. § 103(a) based on Cingotti in view of Breitenbach. Finally, because neither Menzi nor Breitenbach teach a neutral core as recited in the amended claims, Applicants respectfully

request that the Examiner reconsider the rejection under 35 U.S.C. § 103(a) based on Menzi in view of Breitenbach.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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